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§56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

- (c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:
- (1) The electronic product or products for which the exemption has been issued; and
- (2) Such conditions as the Secretary deems necessary to protect the public health and safety.
- (d) Any person who contests denial of an exemption shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[38 FR 28628, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977; 50 FR 7518, Feb. 22, 1985]

## PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELEC-TRONIC PRODUCTS

Sec.

1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

1004.2 Plans for the repair of electronic products.

1004.3 Plans for the replacement of electronic products.

1004.4 Plans for refunding the cost of electronic products.

1004.6 Approval of plans.

AUTHORITY: 21 U.S.C. 360hh-360ss.

Source: 38 FR 28629, Oct. 15, 1973, unless otherwise noted.

## § 1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

(a) If any electronic product fails to comply with an applicable Federal standard or has a defect and the notification specified in §1003.10(b) of this chapter is required to be furnished, the manufacturer of such product shall;

- (1) Without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied; or
- (2) Replace such product with a like or equivalent product which complies with each applicable Federal standard and which has no defect relating to the safety of its use; or
- (3) Make a refund of the cost of the product to the purchaser.
- (b) The manufacturer shall take the action required by this section in accordance with a plan approved by the Secretary pursuant to §1004.6.

## § 1004.2 Plans for the repair of electronic products.

Every plan for bringing an electronic product into conformity with applicable Federal standards or for remedying any defect in such product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

- (a) Identification of the product involved.
- (b) The approximate number of defective product units which have left the place of manufacture.
- (c) The specific modifications, alterations, changes, repairs, corrections, or adjustments to be made to bring the product into conformity or remedy any defect.
- (d) The manner in which the operations described in paragraph (c) will be accomplished, including the procedure for obtaining access to, or possession of, the products and the location where such operations will be performed.
- (e) The technical data, test results or studies demonstrating the effectiveness of the proposed remedial action.
- (f) A time limit, reasonable in light of the circumstances, for completion of the operations.
- (g) The system by which the manufacturer will provide reimbursement for any transportation expenses incurred in connection with having such product brought into conformity or having any defect remedied.